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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FISHER, ABIGAIL L	

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1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/695,347	LI ET AL.	
	Examiner	Art Unit	
	ABIGAIL FISHER	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,17-23 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,17-23 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments/Remarks filed on September 15 2008 is acknowledged. Claims 9-16, 24-27 and 29-31 were/stand cancelled. Claims 1-3 and 17 were amended. Claims 1-8, 17-23 and 28 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 2 and 3 for insufficient antecedent basis is **withdrawn** in light of Applicants' amendments filed on September 15 2008.

The rejection of claims 8 and 23 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in light of Applicants' arguments filed on September 15 2008..

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 6-8, 17-19, 22-23 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choi et al. (WO 9920745) in view of Chen et al. (US Patent No. 5922352) and in further view of Sangekar et al. (US Patent No. 4992277).

Applicant Claims

Applicant claims a dosage form comprising a compressed core and an overcoated shell portion that comprises a composition comprising 40 to 95 weight percent of a water soluble polymer having a cloud point from about 20 to about 90° C, 5 to 25 weight percent carrageenan, and 0.5 to 5 weight percent gellan gum.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Choi et al. is directed to an enteric coated granule. The coated granule contains lactic acid bacteria and is coated with a water-miscible coating material (page 4, first and fourth paragraph). The lactic acid bacteria is prepared by first coating the bacteria-containing seed with a water-miscible coating material and then further coating the first coated product with a second coating (page 4, second paragraph). The water-miscible coating that can be utilized include hydroxypropylmethylcellulose (page 4, fourth paragraph) and gellan gum (page 5, first paragraph). The first coating is utilized in an amount of 1 to 80% by weight (page 5, third paragraph). The second coating material can include one or more coating materials that include hydroxypropylmethylcellulose, carrageenan, and gellan gum (page 6, second paragraph). The one or more materials are utilized in an amount of 1 to 95% by weight (page 8, first paragraph). The coating process is carried about by processes known in the art such as utilizing a fluidized bed granulator, CF-granulator, and the like (page 8, second paragraph).

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Choi et al. do not specify that the coating is made of hydroxypropylmethylcellulose, carrageenan, and gellan gum. Choi et al. do not specify that the core is compressed. Choi et al. do not specify the inclusion of glycerol monostearate. However, these deficiencies are cured by Chen et al.

Chen et al. is directed to enteric coated calcium channel blocker compounds. The granules which form the compressed core contain additionally known excipients such as a tablet lubricant such as glycerol monostearate (column 3, lines 4-17). This

core is then coated with pharmaceutically acceptable polymers such as hydroxypropylmethylcellulose (column 3, lines 1-3).

Choi et al. do not specify the viscosity of the hydroxypropylmethylcellulose or that the formulation exhibits a burst release formulation. However, these deficiencies are cured by Sangekar et al.

Sangekar et al. is directed to an immediate release formulation. The core comprises diltiazem and is coated with a swellable hydrophilic polymer (abstract and column 2, lines 62-65). The hydrophilic polymers utilized include hydroxypropyl methylcellulose which can be used alone or in combination with other hydrocolloids such as guar gum (column 3, lines 1-7). The hydroxypropyl methylcellulose is commercially available in various grades under several trade names including METHOCEL E, METHOCEL F, and METHOCEL K. These commercially available products have viscosities in a 2% aqueous solution ranging from 3500 to 100,000 cps (mPas) (column 3, lines 16-43).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to utilize hydroxypropylmethylcellulose, carrageenan, and gellan gum as the polymers of the coating. One of ordinary skill in the art would have been motivated to utilize these three polymers in the formulation of the second coating as Choi et al. indicates one or more polymers can be utilized and discloses these three polymers as being suitable. Alternatively, it would have been obvious to utilize either hydroxypropylmethylcellulose or gellan gum as the polymer in the first coating and then utilize carrageenan and either

hydroxypropylmethylcellulose or gellan gum as the polymers in the second coating. It would have been obvious to one of ordinary skill in the art to try the polymers listed in Choi et al as a person with ordinary skill has good reason to pursue known options within his or her technical grasp. **Note: MPEP 2141 [R-6]** *KSR International CO. v. Teleflex Inc.* 82 USPQ 2d 1385 (Supreme Court 2007).

It would have been obvious to one of ordinary skill in the art to combine the teachings of Choi et al. and Chen et al. and utilized a compressed core. One of ordinary skill in the art would have been motivated to utilize this type of core because it is know a known type of core utilized in enteric coated formulations as taught by Chen et al. Therefore, there is a reasonable expectation that a compressed core will be suitable in the enteric coated formulation of Choi et al.

It would have been obvious to one of ordinary skill in the art to combine the teaching of Choi et al. and Chen et al. and utilize a lubricant such as glycerol monostearate. One of ordinary skill in the in art would have been motivated to utilize glycerol monostearate because it is a known excipient utilized in formulation of enteric coated formulations.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Choi et al., Chen et al., and Sangekar et al. and utilize commercially available grades of water soluble hydroxypropyl methylcellulose. It would have been obvious to one of ordinary skill in the art to try the commercially available water soluble polymers of Sangekar as a person with ordinary skill has good reason to pursue known

options within his or her technical grasp. **Note: MPEP 2141 [R-6]** *KSR International CO. v. Teleflex Inc.* 82 USPQ 2d 1385 (Supreme Court 2007).

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Regarding the claimed percentages of hydroxypropylmethyl cellulose, carrageen and gellan gum, Choi et al. discloses that the percentages of the coating is from 1 to 80% by weight for the first coating and 1 to 95% by weight of the second coating. It would have been obvious to one of ordinary skill in the art at the time of the invention to engage in routine experimentation to determine optimal or workable ranges that produce expected results. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. **In re Aller, 220 F. 2d 454, 105 USPQ 233 (CCPA 1955).**

Regarding instant claims 8 and 23, Choi et al. is silent as to the pore size, if any, of the coating. Therefore, there is a reasonable expectation that the coating does not contain any pores and therefore meets the limitation of the instant claims.

Regarding the functional limitation that the water soluble polymer has a cloud point form about 20 to about 90 °C, Choi et al. is silent as to the cloud point. However, since the polymer utilized is the same, it is the examiner's position that it would necessarily have the same cloud point as this is a physical property of the chemical

utilized. It is incumbent on Applicant to demonstrate that the hydroxypropyl methylcellulose of Choi et al. does not have the same cloud point as instant claimed.

Regarding the functional limitation that the dosage form is a burst release fashion, Sangekar indicates that hydroxypropyl methylcellulose is utilized in a coating that exhibits immediate release. Therefore, there is a reasonable expectation that utilizing this polymer in the coating of Choi et al. would result in a dosage form that exhibits a burst release. Additionally, Applicant has not defined burst release, therefore as long as **any** of the active is released immediately it would necessarily read on the instant claims.

Response to Arguments

Applicants argue that "burst release" is defined in the specification as release of the active ingredient from the dosage form that is delayed for a pre-determined time after ingestion by the patient after which it is promptly released. Therefore, the claimed "burst release" dosage forms are not encompassed by or even suggested by an immediate release tablet.

Applicants' arguments filed September 15 2008 have been fully considered but they are not persuasive.

Applicants have referred to a specific section in the specification which they argue is a definition of burst release. The examiner respectfully disagrees. This section in the specification describes one specific embodiment and is therefore not a definition. Additionally, if one did consider this section to be a definition it would be a definition of

"delayed burst release" not burst release. Burst release as indicated in this section of the specification can properly be inferred as being a prompt release. This prompt release can then be reasonably interpreted as immediate release.

A delayed release is achieved via a specific polymer or polymers and concentrations of polymer(s) utilized in the shell coating of the dosage form. Choi et al. is directed to an enteric coated granule. Therefore, the active ingredient would not be released until it has reached the intestines which would necessarily then be a delayed release. Since Choi et al. teach the idea of a core with a coating, it is well within the skill of one of ordinary skill in the art to vary the types and amounts of polymers out of those taught in the prior art as being suitable in order to manipulate the release profile of the dosage form.

Therefore, the rejection is maintained since applicant has not provided any persuasive arguments to overcome the rejection.

Claims 4-5 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choi et al. in view of Chen et al. and in further view of Sangekar et al. and Yamamoto et al. (US Patent No. 5756123).

Applicant Claims

Applicant claims that the dosage form further comprises an inorganic cation selected from the group consisting of potassium cations, calcium cations, and mixtures thereof.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

The teachings of Choi et al., Chen et al. and Sangekar et al. are set forth above. Choi et al. is directed to an enteric coated formulation wherein the coating can include polymers such as hydroxypropylmethylcellulose, gellan gum, and carrageen.

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Choi et al. do not specify that inorganic cations can be added. However, this deficiency is cured by Yamamoto et al.

Yamamoto et al. is directed to a capsule sell comprising hydroxypropyl methylcellulose, carrageenan and potassium and/or calcium ions (abstract). It is disclosed that carrageenan is a gelling agent and that the potassium ion is a co-gelling agent. It is disclosed that the shapability of the hydroxypropyl methyl cellulose is improved by blending carrageenan as a gelling and gelling this carrageenan with a co-gelling agent (column 2, lines 43-53).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Choi et al., Chen et al., Sangekar et al. and Yamamoto et al. and utilize potassium ions in the coating. One of ordinary skill in the art would have been motivated to include potassium ions because it was known in the art at the time of the invention that the addition of potassium ions with carrageen improves the shapability of the hydroxypropyl methylcellulose. Therefore, one of ordinary skill in the art would have

been motivated to include potassium in a coating comprising hydroxypropyl methylcellulose and carrageen if they wanted to improve the shapability of the coating.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Mina Haghighatian/
Primary Examiner, Art Unit 1616